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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/899,532	07/06/2001	Leonid Zhelnin	02973.00040	3386

22907 7590 09/30/2003

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EXAMINER
GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/30/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/899,532	ZHELNIN ET AL.	
	Examin r	Art Unit	
	STEPHEN GUCKER	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims **1-8, 12, 38, and 39**, drawn to a method of producing a polypeptide comprising SEQ ID NO: 2, an isolated nucleotide comprising SEQ ID NO: 1, expression vectors, host cells, and pharmaceutical compositions comprising same, classified in class 435, subclass 69.1, for example.

II. Claims **9, 10, and 11**, drawn to a purified polypeptide comprising SEQ ID NO: 2 and fusion proteins comprising same, classified in class 530, subclass 350, for example.

III. Claims **13-15**, drawn to a method of detecting a coding sequence for a polypeptide comprising SEQ ID NO: 2 comprising the steps of hybridizing to nucleic acid material of a biological sample, classified in class 435, subclass 6, for example.

IV. Claims **16 and 17**, drawn to a method of detecting a polypeptide comprising SEQ ID NO: 2 comprising the steps of contacting a biological sample with an antibody, classified in class 435, subclass 7.1, for example.

V. Claims **18-26 and 28 (in part)**, drawn to a method of screening for agents that can regulate the activity of an neuropeptide Y-like G protein-coupled receptor, comprising the steps of contacting a test compound with a polypeptide comprising SEQ ID NO: 2, classified in class 435, subclass 7.1, for example.

VI. Claims **27 and 29 (each in part)**, drawn to a method of screening for agents that can regulate the activity of an neuropeptide Y-like G protein-coupled receptor, comprising the steps of contacting a test compound with a product encoded by a polynucleotide comprising SEQ ID NO: 1 where said product is RNA, classified in class 435, subclass 7.1, for example.

VII. Claims **30-32**, drawn to a method of reducing expression of an NPY-like GPCR comprising the steps of contacting a cell with an antibody, classified in class 424, subclass 130.1, for example.

VIII. Claims **33-35**, drawn to a method of reducing expression of an NPY-like GPCR comprising the steps of contacting a cell with an antisense nucleotide, classified in class 514, subclass 44, for example.

IX. Claim **36 and 41-43**, drawn to an antibody and pharmaceutical compositions comprising same, classified in class 530, subclass 387.1, for example.

X. Claim **37**, drawn to an antisense nucleotide and pharmaceutical compositions comprising same, classified in class 536, subclass 24.5, for example.

XI. Claim **40**, drawn to a method of treating obesity, classification dependent upon agent structure.

2. The inventions are distinct, each from the other because of the following reasons:

3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions

for the following reasons: Inventions I, III, IV, V, VI, VII, VIII, and XI are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of recombinant expression of SEQ ID NO: 1, which is not required by any of the other Inventions. Invention III requires search and consideration of determining the presence of a nucleic acid molecule in a sample, which is not required by any of the other Inventions. Invention IV requires search and consideration of determining the presence of a polypeptide in a sample, which is not required by any of the other Inventions. Invention V requires search and consideration of a screening method using SEQ ID NO: 2, which is not required by any of the other Inventions. Invention VI requires search and consideration of a screening method using the RNA encoded by SEQ ID NO: 1, which is not required by any of the other Inventions. Invention VII requires search and consideration of reducing expression of an NPY-like GPCR using an antibody, which is not required by any of the other Inventions. Invention VIII requires search and consideration of reducing expression of an NPY-like GPCR using antisense, which is not required by any of the other Inventions. Invention XI requires search and consideration of treating obesity, which is not required by any of the other Inventions.

4. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Inventions II, IX, and X are directed to products that are distinct both physically and functionally, are not required one for the other, and are therefore patentably distinct.

5. The polypeptide of Invention II can be prepared by processes which are materially different from the antibody of Invention IX and the antisense molecule of Invention X, such as by chemical synthesis.

6. Although the antibody of Invention IX can be used to obtain the polypeptide of Invention II, it can also be used in materially different methods, such as in various diagnostic (e.g., as a probe in immunoassays or immunochromatography), or therapeutic methods. The antisense molecule of Invention X is not required to make or use the antibody of Invention IX.

7. Additionally, the antisense of Invention X can be used other than to make the polypeptide of Invention II, such in gene therapy or as a probe in nucleic acid hybridization assays. The antibody of Invention IX is not required to make or use the antisense molecule of Invention X.

8. Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the polypeptide of Invention II could be made using materially different processes such as isolation from natural sources or chemical synthesis.

9. Inventions II and each of IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Invention II could be used in materially different processes such as a therapeutic or to make antibodies.

10. Inventions IX and each of IV and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Invention IX could be used in materially different processes such as to purify the polypeptide of Invention II.

11. Inventions X and each of III, VI, and VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antisense molecule of Invention X could be used in materially different processes such as to reverse transcribe a cDNA.

12. Inventions II and each of III, IV, VII, VIII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions II and each of III, IV, VII, VIII, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions III, IV, VII, VIII, and XI do not recite the use or production of the polypeptide of Invention II.

13. Inventions IX and each of I, III, V, VI, VIII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP §

808.01). In the instant case the different inventions of Inventions IX and each of I, III, V, VI, VIII, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, III, V, VI, VIII, and XI do not recite the use or production of the antibody of Invention IX.

14. Inventions X and each of I, IV, V, VII, and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of Inventions X and each of I, IV, V, VII, and XI are unrelated product and methods, wherein each is not required, one for another. For example, the claimed methods of Inventions I, IV, V, VII, and XI do not recite the use or production of the antisense of Invention X.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Stephen Gucker, Ph.D.** whose telephone number is 703-308-6571. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Gary Kunz, Ph.D.** can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN
September 28, 2003

Gary S. Kunz

GARY KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600